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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,452	12/30/2003	Michael J. Bonnette	POSSIS	2399

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EXAMINER	
JOHNSON, JERROLD D	

ART UNIT	PAPER NUMBER
3728	

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/748,452	BONNETTE ET AL.	
	Examiner	Art Unit	
	Jerrold Johnson	3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 and 11-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 11-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The cancellation of claims 1-8 and 10 is acknowledged.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35 USC 103(a)

1. Claims 9,11-14, and 18-24 are rejected under as being unpatentable over George US 5,014,494 in view of Erbe et al. US 6,736,799.

Re claim 9, George provides a plastic/foil laminate sealable container storage arrangement for oxygen-sensitive plastic medical articles (typically syringes) that need to undergo gamma radiation in the absence of oxygen, lest they also be subject to

deterioration through yellowing. George discloses the isolation of the medical article from ambient atmosphere while the article is in the container. And, George discloses several polymer plastics by example which are known to yellow post gamma radiation. For those plastics that yellow in the presence of oxygen post gamma radiation, yellowing will occur in the package of George should the package be opened within the time window that the plastic is sensitive to oxygen. Additionally, George impliedly suggests that more than one oxygen sensitive article be disposed in the container. See the use of "articles" throughout the disclosure, and claim 6. Accordingly, George inherently discloses both an oxygen sensitive product, and an oxygen-sensitive material which provides a visual oxygen sensing indicator (another oxygen-sensitive medical article), or at the very least it would be obvious to one of ordinary skill in the art to provide two or more articles in the storage arrangement of George in response to the teachings provided within his patent.

George explicitly states his objective to provide packaging for medical articles that when subjected to radiation sterilization will not be discolored. See col. 1, lines 45-50.

George does not explicity set forth that the oxygen sensitive materials are inactive prior to exposure to radiation and activatible by exposure to radiation, the activation of the oxygen sensitive material causing the oxygen sensitive material to become sensitive to oxygen exposure only after activation and to remain sensitive to oxygen exposure after completion of radiation exposure and to undergo a visual change in response to subsequent contact with oxygen.

Applicant has indicated in the specification that the oxygen sensitive material that has the aforementioned characteristics is Dow 2081 polycarbonate.

Erbe in col. 7 discloses the use of Dow 2081 in a syringe. Dow 2081 is a polycarbonate material specifically designed for medical devices subject to gamma radiation sterilization. Specifically, Dow 2081 is recognized as being "gamma stabile." Because the syringe of Erbe is constructed from Dow 2081, it is submitted that the syringe of Erbe inherently possesses the oxygen sensitive characteristics set forth in the claim 9.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to use syringes constructed of "gamma stabile" Dow 2081 as taught by Erbe in the storage arrangement of George, so as to provide a syringe that is discolored as little as possible by the gamma radiation sterilization. Specifically, the motivation of the use of this material is that this material has been developed specifically for the purpose of gamma radiation sterilization, and that it undergoes a minimum of color change during gamma radiation. This motivation is, again, perfectly in line with the objectives of George set forth in col. 1, lines 45-50.

In an attempt to further understand the properties of Dow 2081 the Examiner contacted Nancy Hermanson at Dow Chemical on 30 March 2006. Ms. Hermanson was asked a single question "what are the recommendations set forth by Dow with respect to exposure to oxygen during gamma radiation." Ms. Hermanson replied that Dow does not make any recommendations, but that some manufactures recommend that gamma radiation be conducted in the absence of oxygen, and that some

manufactures have found that the presence of oxygen during gamma radiation is not a significant concern. No further questions were asked of Ms. Hermanson. As would be expected, none of the details of the present application were discussed.

From this extrinsic evidence, the use of a syringe manufactured from Dow 2081 as is disclosed by Erbe within the package of George would be consistent with the teachings of many manufacturers of medical devices constructed from Dow 2081 who believe that products manufactured from this material should be radiated in the absence of oxygen.

With respect to Applicant's arguments, the Examiner is well aware that the combination relied upon in the Examiner's rejection (George in view of Erbe) would be motivated for reasons (to provide the package of George with a syringe specifically manufactured to undergo a minimum of changes, particularly in material color during gamma radiation, which is exactly the goal of George) that are different than those set forth in the present application (as a means to reveal the presence of oxygen). There is nothing improper about inconsistency. The combination of the references (George in view of Erbe) is proper for the previously set forth reasons, even though those reasons are clearly different from those at the basis of the present application. And, as is stated above, this combination of references inherently possess the properties that are set forth in claim 1. Specifically, claim 1 does not set forth any limitations that are not present expressly or inherently in this combination of references, and the rationale behind the combination of the references is sound.

Re claim 11, another medical device other than the first device meets this language. With respect to the use of the limitation "fixed", and the arguments presented with respect to this limitation, it is submitted that an element disposed within a sealed package, as taught by George, is fixed within the package. The expression "fixed" is not set forth with enough specificity to define over what is taught by George.

Re claim 12, George in view of Erbe further inherently discloses a storage arrangement wherein the visual change of the oxygen-sensitive material indicates a failure of the sealable container. Specifically, if the container has failed and oxygen is let into the container a change in color of the polycarbonate portion of the syringe (per the teaching of Erbe) will be evident.

Re claims 13 and 14, George discloses various polymer plastics by way of example in col. 2, lines 28 and 29. And, Erbe discloses the exact polymer polycarbonate plastic used by the applicant.

Re claim 18, the portion 21 of the barrel 20 comprises a generally planar chip as is broadly set forth in this claim. This portion of the syringe would n ecessarily be disposed adjacent to a backing (the tray) during sterilization. The proximity of the chip 21 to the backing material would inherently provide the enhanced visibility of the visual change as is set forth.

Re claims 19 and 20, Erbe inherently possesses these characteristics.

Re claim 21, George and Erbe disclose medical devices.

Re claim 22, the color change formed on the medical device is the symbol that assists in interpreting the visual change.

Re claims 23 and 24, George discloses a purged "initially oxygen poor" atmosphere, along with the other claimed features set forth in claim 9 rejected above.

3. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over George US 5,014,494 in view of Erbe US 6,736,799 and further in view of Nicolais US 6,161,695, Ahlqvist et al US 5,881,534 and Examiner Official Notice.

George does not explicitly set forth the plastic/foil laminate as set forth in claims 16 and 17, but does disclose in col. 2, line 47, impermeable containers using foil which are necessary for the sterilization in the absence of oxygen.

Nicolais, discloses a gas-impermeable foil pouch having a polymer/foil construction (the well known construction of impermeable pouches) and an outer cardboard protective packaging. Nicolais does not disclose the exact foil pouch laminate as set forth in claim 17. However, it is submitted that this laminate is known in the prior art, as there are literally hundreds of such laminates used in the medical industry. And, Applicant devoted a single sentence to this laminate, which suggests that this laminate is merely an off the shelf laminate known in the art.

Ahlqvist discloses in col. 8 lines 1-12 laminates having PET layers, and the known irradiation dose of 35 kGy, which is a common radiation dose used in sterilization of medical devices.

Accordingly, it would have been obvious to modify the container of George with the teachings of using a multiple medical devices in the sealed container during sterilization, so that if oxygen is present and the device yellows, the situation will be easily visually identified.

Additionally it would have been further obvious to have used a gas-impermeable foil pouch within a cardboard packaging, as disclosed by Nicolais, as such foil pouches are known for their impermeability to air, a necessity set forth by George, and to protect the pouch with a cardboard packaging to protect the foil pouch from puncture.

With respect to claim 15, it would be obvious to use a range for the amount of gamma radiation from 25 kGy to 45 kGys as disclosed by Ahlqvist, as that is the range commonly used to sterilize medical devices, and is within the capabilities of the equipment already used for this purpose.

With respect to the specific laminate set forth in claim 17, the Examiner submits that such a laminate is well known in the art. For economic reasons, it would be obvious to use a known polymer foil laminate in the construction of the pouch.

The following prior art is considered pertinent to applicant's disclosure. This prior art is made of record but has not been relied upon in the previous rejections.

MD & DI August 1997 Column discusses the color changes in Dow 2081 during gamma radiation.

Sleeckx US 6,166,116, assigned to Dow Chemical, discloses in columns 9 and 10 the testing of 10 chips of polycarbonate in sealed packages during gamma irradiation, and the subsequent opening of the packages so as to measure color change.

Conclusion

Applicant's arguments drawn to claim limitation have been set forth above within the body of the rejections. It is submitted that the specific utility of the applicant's invention, as is disclosed in the specification of the present application, is not taught in the prior art currently of record. However, the claims drawn to the invention are rendered obvious for reasons fully explained above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerrold Johnson whose telephone number is 571-272-7141. The examiner can normally be reached on 9:30 to 6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDJ

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